K052521

SEP 26 2005

510(k) Summary: NISSIN Mechanical Wheelchair

Summary of Safety and Effectiveness:

Submitted: September 7, 2005

Name of Firm: NISSIN MEDICAL INDUSTRIES (NISSIN) Company, LTD
Darren Reeves, U.S. Agent
Location: 8-7 Hanenishi
Yoyohasi, Aichi-Prefecture, Japan

510(k) Contact: Darren Reeves
866-393-4954

Trade Name: NISSIN series Mechanical Wheelchair

Common Name: Mechanical Wheelchair

Classification: 21 CFR Part 890.3850 Mechanical wheelchair

Device Product Code: IOR.

Substantially Equivalent Device: Quickie Suspension Wheelchair Series Model XTR by Sunrise Medical (K982989)

Device Description:

The NISSIN series Mechanical Wheelchair consists of typical components found on most wheelchairs, such as push handles, armrests, backrest, seat frame, cushion, footrest and casters. Many of these components are available in a range of sizes, shapes, angles, forms, materials or coverings. Theses variations allow the chairs to be configured to meet the specific desires and needs of the user.

Intended Use:

The NISSIN series Mechanical Wheelchair is intended to be used to empower persons physically challenged to a sitting position by providing a means of mobility.

Summary of Safety and Effectiveness:

Data was provided that demonstrated compliance with the **Guidance document for the preparation of premarket notification [510(k)] applications for mechanical and powered wheelchairs, and motorized three-wheeled vehicles (July 26, 1995, reformatted 12/18/97).** In addition, data was submitted that demonstrated compliance with ISO 7176. All issues of safety and effectiveness have been addressed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2005

Nissin Medical Industries Company, LTD
c/o Mr. Darren Reeves
DP Distribution & Consulting
15637 Fox Cove Circle
Moseley, Virginia 23120

Re: K052521
Trade/Device Name: Mechanical Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: September 12, 2005
Received: September 14, 2005

Dear Mr. Reeves:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K052521**

Device Name: **Mechanical Wheelchair**

Indications For Use:

Intended for medical purposes to provide mobility to persons restricted to a sitting position

Prescription Use _____ AND/OR Over-The-Counter Use ____X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Registration and Listing are submitted and in process)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052521